RETURN TO SERVICE PROCEDURE TABLE OF CONTENTS
RETURN TO CD-ROM TABLE OF CONTENTS

Dräger medical
A Dräger and Siemens Company

Field Service Procedure

Part Number: SP00175
Rev: D
Date: 20 September 2003

Periodic Manufacturer's Certification Forms

RETURN TO SERVICE PROCEDURE TABLE OF CONTENTS
RETURN TO CD-ROM TABLE OF CONTENTS

Periodic Manufacturer's Certification Forms

PERIODIC MANUFACTURER'S CERTIFICATION

The following pages contain illustrations of Periodic Manufacturer's Certification (PMC) forms and labels to assist the Technical Service Representative in identifying and completing this documentation.

Pages 2 through 8 illustrate sample checklists with typical periodic maintenance items filled in including vapor concentration tests, parts replaced, general comments and certification level.

Page 9 illustrates reverse side of the PMC forms with equipment condition and corresponding DMI recommended correction.

Page 10 illustrates sample PMC labels marked to show several levels of certification.

Pages 11 and 12 show DMI part numbers for various forms and labels.

Pages 13 through 18 show applicable standards for the components used in anesthesia systems.

Pages 18 through 19 show a sample of the Executive Summary furnished to the customer when a PMC is completed.

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

SP17502

Dräger medical
A Dräger and Siemens Company

NARKOMED ☐2B ☒2C ☐GS
ANESTHESIA SYSTEM

DrägerService is a division of Draeger Medical, Inc. 3122 Commerce Drive Telford, PA 18969 / USA (215) 721-5402 (800) 4-DRAGER (215) 723-5935 FAX

INSTITUTION GENERAL HOSPITAL
ADDRESS 123 MAIN STREET
CITY ANYTOWN STATE PA ZIP 18970
TELEPHONE (610) 368-4361 CONTACT Dr. Jones

SOFTWARE VERSION NUMBER 1.3
MACHINE SERIAL NUMBER 13695
ROOM NUMBER 8
P.O. NUMBER 73684
DISPATCH NUMBER 36915

☒ Verify Test Equipment Due Dates
☒ SP00062 Vent Valve Lube Due (H)
☒ SP00075 Relief Valve Diaphragm Due 08-03
☒ Dräger Vaporizer Verification SP00073
☐ DES Vaporizer Verification SP00091/SP00189

☒ **6.1 SELF DIAGNOSTICS**

☒ **6.2 ELECTRICAL SAFETY - DUE** 08-03
☒ 6.2.1 Ground Continuity
☒ 6.2.2 Circuit Isolation
☒ 6.2.3.3 Chassis Leakage Current

Ground	Polarity	
Normal	Normal	0 µA
Open	Normal	10 µA
Open	Reversed	10 µA
Normal	Reversed	0 µA

☒ 6.2.4 Convenience Receptacle & Outlet Strip

☒ **6.3 CONFIGURATION**

6.4 SERVICE DATA
☒ 6.4.8 Reset Service Date
☒ 6.4.10 Next Service - Due 11-02

6.5 CALIBRATIONS - DUE 8-03
☒ 6.5.3 O2 Analyzer Zero Calibration
☒ 6.5.10 Pressure Zero & Span Calibration

☒ **6.6 ABSORBER MAINTENANCE**

☒ **6.7 HIGH PRESSURE LEAK**

6.8 BREATHING SYSTEM
☒ 6.8.1.8 Fresh Gas Leak
☒ 6.8.1.10 Left Vaporizer Leak
☒ 6.8.1.12 Center Vaporizer Leak
☒ 6.8.1.14 Right Vaporizer Leak
☒ 6.8.1.15 Vapor Exclusion System
☒ 6.8.2.4 Absorber APL Valve
☒ 6.8.3.5 O2 Flush Rate
☒ 6.8.4.5 Expiratory Valve Leak
☒ 6.8.5.7 Inspiratory Valve Leak
☒ 6.8.6.10 PEEP Max Pressure
☐ 6.8.7.10 Bain Adapter Leak
☐ 6.8.7.14 Bain APL Valve

6.9 OXYGEN ANALYZER
☒ 6.9.2 O2 Calibration
☒ 6.9.14 O2 Flow Concentration

6.10 FLOWMETER CONCENTRATIONS
☒ 6.10.1 Oxygen Flowmeter
☐ 6.10.2 Oxygen-Helium Flowmeter
☐ 6.10.3 Helium Flowmeter
☐ 6.10.4 Nitrogen Flowmeter
☒ 6.10.5 Carbon Dioxide Flowmeter
☒ 6.10.6 Air Flowmeter
☒ 6.10.7 Nitrous Oxide Flowmeter
☒ 6.10.8.2 ORC @ 4L / min.
☒ 6.10.8.4 ORC @ 2L / min.
☒ 6.10.8.6 ORC @ 1L / min.
☐ 6.10.9.8 ORMC @ 1L / min.
☐ 6.10.9.10 ORMC @ 2L / min.
☐ 6.10.9.12 ORMC @ 4L / min.
☒ 6.10.10 Auxiliary Oxygen Flowmeter

6.11 HIGH PRESS. REG - DUE 02-03
☒ 6.11.1.7 N2O Regulator
☒ 6.11.2.6 Air Regulator
☒ 6.11.3.6 O2 Regulator

☒ **6.12 LOW O2 SUPPLY - DUE** 02-03

6.13 O2 SUPPLY FAILURE PROTECTION
☒ 6.13.3 Minimum O2 Flow
☒ 6.13.5 N2O Bypass Flow @ Min. O2
☒ 6.13.8 O. F.P.D. Verification

6.14 PRESSURE MONITOR
☒ 6.14.5 APNEA Pressure Caution
☒ 6.14.6 APNEA Threshold
☒ 6.14.8 CONTINUOUS PRESS Warning
☒ 6.14.9 CONTINUOUS Threshold
☒ 6.14.10 VENT PRESS HI Threshold
☒ 6.14.11 SUB ATM PRESSURE Threshold

6.15 VENTILATOR
☐ 6.15.9 Extended Range I:E Ratio
☒ 6.15.10 I:E Ratio
☐ 6.15.19 PLC @ 30
☐ 6.15.20 PLC @ MIN
☒ 6.15.22 Reverse Flow
☒ 6.15.28 APNEA - VOLUME Caution
☒ 6.15.32 Flow Direction Check
☒ 6.15.33 Volume Monitor Accuracy

6.16 BELLOWS ADULT
☒ 6.16.1 1200 ml Tidal Volume
☒ 6.16.2 Bellows Inflation Check
☒ 6.16.7 Drive Gas Leakage
☒ 6.16.14 Max Tidal Volume
☒ 6.16.15 Relief Valve PEEP
☒ 6.16.21 200 ml Tidal Volume

6.17 BELLOWS PEDIATRIC EXTERNAL
☐ 6.17.4 Bellows Inflation Check
☐ 6.17.7 Max Tidal Volume
☐ 6.17.9 100 Tidal Volume
☐ 6.17.12 Relief Valve PEEP
☐ 6.17.20 Drive Gas Leakage

6.18 BELLOWS PEDIATRIC INTERNAL
☐ 6.18.3 Bellows Inflation Check
☐ 6.18.6 Max Tidal Volume
☐ 6.18.8 100 Tidal Volume
☐ 6.18.10 Relief Valve PEEP
☐ 6.18.17 Drive Gas Leakage

☒ **6.19 OPEN RESERVOIR - DUE** 02-03
☐ **6.20 A / C SCAVENGER - DUE**
☐ **6.21 BAG SCAVENGER - DUE**
☒ **6.22 SUCTION REGULATOR - DUE** 02-03
☒ **6.23 MANUAL SPHYGMOMETER - DUE** 02-03

6.24 FINAL TESTS
☒ 6.24.1 Operator's Instruction Manual

VAPOR CONCENTRATION VERIFICATION

SERIAL NUMBER	TYPE (H,E,I,S)	1.0 VOL % RIKEN	2.5 VOL % RIKEN	4.0 VOL % RIKEN	RECOMMENDED FOR USE YES	RECOMMENDED FOR USE NO
+AREJ-1234	H	1.07	2.53	4.11	X	
ARFP 3456	I	1.07	2.55	4.09	X	
ARHK 4315	S	1.02	2.76	4.26	X	

TEST EQUIP.

DEVICE	CAL DUE	ID	DEVICE	CAL DUE	ID
BIOTEK 501	11/02	7342	FLOWMETER	06/03	0081
MULTI-METER	2/03	2733			
SENSYM.	11/02	2212			
RIKEN 1814	10/02	0424			
TEST GAUGE	4/03	0063			
VOLUMETER	4/03	2300			

PARTS REPLACED

PARTS DESCRIPTION	PART NUMBER	WHSE	QTY	C/ CS/ N
BELLOWS SUB ASM	4106930-001	409	1	N/A

RECOMMENDATIONS/ GENERAL COMMENTS: SEE EQUIPMENT CONDITION NUMBER 30

CERTIFICATION LEVEL	
LAST VISIT	B
THIS VISIT	B
NEXT VISIT DUE	11/02

T. S. R. Signature John Green | I. D. No. E-409 | Time 6:00pm | Customer Signature Drew Jones, MD | Date 8/10/02

REGULATORY AFFAIRS

S010211 REV L

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

SP17503

Dräger medical
A Dräger and Siemens Company

FABIUS GS
ANESTHESIA SYSTEM

DrägerService is a division of Draeger Medical, Inc. 3122 Commerce Drive Telford, PA 18969 / USA (215) 721-5402 (800) 4-DRAGER (215) 723-5935 FAX

INSTITUTION GENERAL HOSPITAL
ADDRESS 123 MAIN STREET
CITY ANYTOWN STATE PA ZIP 18970
TELEPHONE (610) 368-4361 CONTACT Dr. Jones

SOFTWARE VERSION NUMBER 1.01
MACHINE SERIAL NUMBER 12385
ROOM NUMBER 8
P.O. NUMBER 73684
DISPATCH NUMBER D7643CF2

7.1 ELECTRICAL SAFETY
- ☒ 7.1.1 Protective Ground Continuity
- ☒ 7.1.2 Circuit Isolation
- ☒ 7.1.3 Auxiliary Outlet Strip ☐ n/a
- ☒ 7.1.4.3 Chassis Leakage Current
  - Open/Normal 10 µA
  - Normal/Normal 0 µA
  - Open/Reverse 10 µA
  - Normal/Reverse 0 µA

☒ 7.2 SYSTEM DIAGNOSTICS
☒ 7.3 BATTERY CIRCUIT
☒ 7.4 CONFIGURATION

7.5 SERVICE DATA
- ☒ 7.5.2 Last Service Date 7-10-02
  - Hours Since Service 100
  - Total Hours 200
  - Total Ventilator Hours 150
- ☒ 7.5.7 Ventilator O-Ring

7.6 CALIBRATIONS
- ☒ 7.6.4 Fresh Gas Flow
- ☒ 7.6.7 Pressure
- ☒ 7.6.9 O2 Offset
- ☒ 7.6.11 PEEP

7.7 SITE CONFIGURATIONS
- ☒ 7.7.2 O2 Position (virtual) L
- ☒ 7.7.3 Gas Selection 3
- ☒ 7.7.5 O2 Whistle ON
- ☒ 7.7.6 No Fresh Gas ON
- ☒ 7.7.7 Fresh Gas Low Alarm ON
- ☒ 7.7.8 Threshold Low Alarm ON
- ☒ 7.7.9 Ambient Pressure 1013 mbar
- ☒ 7.7.12 Serial Ports

☒ 7.8 SCAVENGER – AGS

7.9 BREATHING SYSTEM
- ☒ 7.9.1 Breathing System Inspection
- ☒ 7.9.1.1 Breathing System S/N ARCC-1358

7.9.2 FRESH GAS LEAK
- ☒ 7.9.2.6 Fresh G. Leak 2 cm/H2O
- ☒ 7.9.2.9 Frsh G. Lk L/vap 2 cm/H20 ☐ n/a
- ☒ 7.9.2.11 F.G. Lk R/vap 2 cm/H2O ☐ n/a

☒ 7.9.3 BREATHING SYSTEM

7.9.4 APL VALVE
- ☒ 7.9.4.6 APL Valve 10 cm/H20
- ☒ 7.9.4.7 APL Valve 10.44 cm/H20

7.9.5 INHALATION AND EXHALATION VALVES
- ☒ 7.9.5.6 Inh. valve leak 25 cc/min
- ☒ 7.9.5.12 Exh. valve leak 15 cc/min

7.9.6 FRESH GAS DECOUPLING VALVE
- ☒ 7.9.6.7 Fresh Gas Decl Valve Leak 5 ml/min

7.9.7 LEAKAGE CONTROL PORT
- ☒ 7.9.7.5 Leakage Control Port 5 cc/min

☒ 7.10 VAPOR INTERLOCK SYSTEM

7.11 YOKES & GAUGES ☐ n/a
- ☒ 7.11.1 Yokes & Gauges
- ☒ 7.11.2 Cylinder Gauges ☐ n/a

7.12 GAS INLET REGULATOR OUTPUT
- ☒ 7.12.1.5 O2 Inlet Regulator 30 psi
- ☒ 7.12.2.4 N2O Inlet Reg. 30 psi ☐ n/a
- ☒ 7.12.3.4 O2 Pipeline Chk Valve 2 cc/min
- ☒ 7.12.3.6 N2O Pipeline Chk Valve 2 cc/min ☐ n/a
- ☒ 7.12.3.8 Air Pipeline Chk Valve 2 cc/min

7.13 CYL. REGULATOR & PIPELINE GAUGES
- ☒ 7.13.1 N2O Cylinder Regulator ☐ n/a
- ☒ 7.13.1.8 N2O Cylinder Regulator 35 psi
- ☒ 7.13.2 N2O Gauge
- ☒ 7.13.2.4 N2O Gauge Accuracy
- ☒ 7.13.3.3 N2O Pipeline Leak 2 psi
- ☒ 7.13.4 Air Cylinder Regulator ☐ n/a
- ☒ 7.13.4.7 Air Cylinder Regulator 30 psi
- ☒ 7.13.5 Air Pipeline Gauge Accuracy
- ☒ 7.13.6.3 Air Pipeline Leak
- ☒ 7.13.7 O2 Cylinder Regulator
- ☒ 7.13.7.7 O2 Cylinder Regulator 30 psi
- ☒ 7.13.8 O2 Pipeline Gauge Accuracy
- ☒ 7.13.9.2 O2 Pipeline Leak 2 psi

7.14 HIGH PRESSURE LEAK
- ☒ 7.14.1.6 O2 High Pressure Leak
- ☒ 7.14.3.7 N2O High Pressure Leak ☐ n/a
- ☒ 7.14.3.7 Air High Pressure Leak ☐ n/a

7.15 OXYGEN SUPPLY FAILURE PROTECTION
- ☒ 7.15.1 N2O ☐ n/a
- ☒ 7.15.2.5 O2 Supply Press. Alarm 20 psi
- ☒ 7.15.2.6 O2 SUPPLY LOW – Alarm

7.16 FLOWMETERS
- ☒ 7.16.1 O2 Flowmeter
- ☒ 7.16.2 N2O Flowmeter ☐ n/a
- ☒ 7.16.3 Air Flowmeter
- ☒ 7.16.4 Aux/O2 Flowmeter ☐ n/a
- ☒ 7.16.4.5 Aux/O2 leakage 50 cm/H2O
- ☒ 7.16.4.10 Aux/O2 Concentration 99 %O2

☒ 7.17 OXYGEN MONITOR
- ☒ 7.17.12 INSP O2 LOW Alarm
- ☒ 7.17.20 INSP O2 HIGH Alarm
- ☒ 7.17.23 O2 Concentration 99 %O2

7.18 OXYGEN CONCENTRATIONS
- ☒ 7.18.1. O2/N2O Concentration ☐ n/a
- ☒ 7.18.1.5 O2/N2O Concentration 67 %O2
- ☒ 7.18.1.7 O2/N2O 4.2 L/min
- ☒ 7.18.1.8 Total Flowmeter 5.0 L/min
- ☒ 7.18.2 O2/Air Concentration
- ☒ 7.18.2.4 O2/Air Concentration 75 %O2

7.19 SORC
- ☒ 7.19.4 SORC@ 0.8L/minO2 25 %O2
- ☒ 7.19.6 SORC@ 1.5L/minO2 25 %O2
- ☒ 7.19.8 SORC@ 2.0L/min O2 25 %O2
- ☒ 7.19.10 SORC@ 10L/min O2 25 %O2
- ☒ 7.19.11 SORC Low Flow 0.7 L/min
- ☒ 7.19.13 SORC-N2O Lift-Off 0.1 L/min

7.20 PRESSURE MONITOR
- ☒ 7.20.13 APNEA PRESSURE (med) 15 sec
- ☒ 7.20.14 APNEA PRESSURE (high) 30 sec
- ☒ 7.20.16 Apnea P. Setting 8 cm/H2O
- ☒ 7.20.19 CONT. PRES. 15 sec
- ☒ 7.20.20 Cont. Pres. Setting 17 cm/H2O
- ☒ 7.20.22 Aw PRES. HIGH Alarm 40 cm/H2O
- ☒ 7.20.25 PRES. NEG. Alarm -6 cm/H2O

7.21 VENTILATOR
- ☒ 7.21.1 Manual Ventilation
- ☒ 7.21.2 Spontaneous Breathing
- ☒ 7.21.3 Flow Sensor Zeroing
- ☒ 7.21.4 Ventilator Delivery
- ☒ 7.21.4.11 Volume Delivery @ 380Vt 400 mL/min
- ☒ 7.21.4.12 Volume Accuracy
- ☒ 7.21.5.2 PEEP Accuracy
- ☒ 7.21.6.3 Pmax Accuracy
- ☒ 7.21.7.4 APL Accuracy @ 30 cm/H2O 30 cm/H2O
- ☒ 7.21.7.6 APL Accuracy @ Spont 2 cm/H2O
- ☒ 7.21.10 Pressure Limit Valve 75 cm/H2O
- ☒ 7.21.11.1 Auxiliary Air Valve 7.5 cm/H2O
- ☒ 7.21.12.5 Piston Chamber Leak 10 mL/min
- ☒ 7.21.13.3 Vacuum Pressure 200 cm/H2O

7.22 VOLUME ALARMS
- ☒ 7.22.6 MINUTE VOLUME LOW
- ☒ 7.22.9 APNEA FLOW (med) 15 sec
- ☒ 7.22.10 APNEA FLOW (high) 30 sec
- ☒ 7.22.12 FLOW SENSOR FAIL Alarm
- ☒ 7.22.17.3 Fresh Gas Low Alarm

☒ 7.23 Audio Silence

7.24 Oxygen Flush
- ☒ 7.24.8 Oxygen Flush 99 %O2
- ☒ 7.24.12 Oxygen Flush Rate 50 L/min

7.25 Final Tests
- ☒ 7.25.1 Operator's Manual
- ☒ 7.25.2 Lamp Test
- ☒ 7.25.3 Final Check

VAPOR CONCENTRATION VERIFICATION

SERIAL NUMBER	TYPE (H,E,I,S)	1.0 VOL % RIKEN	1.0 VOL % MULTI	2.5 VOL % RIKEN	2.5 VOL % MULTI	4.0 VOL % RIKEN	4.0 VOL % MULTI	RECOMMENDED FOR USE YES	RECOMMENDED FOR USE NO
+ARCH-1234	H	1.07		2.53		4.11		X	
ARCK 9999	S	1.02		2.67		4.25		X	

TEST EQUIP.

DEVICE	CAL DUE	ID	DEVICE	CAL DUE	ID
BIOTEK 501	11/02	746	VOLUMETER	11/02	893
SENSYM.	11/02	782	FLOWMETER	11/02	400
RIKEN 1814	10/02	763			
TEST GAUGE	4/02	006			

PARTS REPLACED

PARTS DESCRIPTION	PART NUMBER	WHSE	QTY	C/C S/N

RECOMMENDATIONS/ GENERAL COMMENTS: NO RECOMENDATIONS

CERTIFICATION LEVEL	
LAST VISIT	A
THIS VISIT	A
NEXT VISIT DUE	7/02

T. S. R. Signature John Green | I. D. No. E-409 | Time 6:00pm | Customer Signature Drew Jones, MD | Date 1/5/02

☐ REGULATORY AFFAIRS

4117715 REV A

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

SP17504

Dräger medical
A Dräger and Siemens Company

NARKOMED 4
ANESTHESIA SYSTEM

DrägerService is a division of Draeger Medical, Inc. 3122 Commerce Drive Telford, PA 18969 / USA (215) 721-5402 (800) 4-DRAGER (215) 723-5935 FAX

INSTITUTION GENERAL HOSPITAL
ADDRESS 123 MAIN STREET
CITY ANYTOWN STATE PA ZIP 99999
TELEPHONE (215) 555-1212 CONTACT Dr. Jones

SOFTWARE VERSION NUMBER 2.11
MACHINE SERIAL NUMBER 11111
ROOM NUMBER OR 1
P.O. NUMBER 12345
DISPATCH NUMBER UPM1111111

☒ Verify Test Equipment Due Dates
☒ SP00062 Vent Valve Lube Due 12/04
☒ SP00075 Relief Valve Diaphragm Due 12/04
☒ Dräger Vaporizer Verification SP00073
☒ DES Vaporizer Verification SP00091/SP00189

☒ 6.1 SELF DIAGNOSTICS

6.2 ELECTRICAL SAFETY - DUE 12/04
☒ 6.2.1 Ground Continuity
☒ 6.2.2 Circuit Isolation
Chassis Leakage Current

	Ground	Polarity	
☒ 6.2.3.3.1 Normal	Normal	0	µA
☒ 6.2.3.3.2 Open	Normal	45	µA
☒ 6.2.3.3.3 Open	Reversed	47	µA
☒ 6.2.3.3.4 Normal	Reversed	0	µA

☒ 6.2.4 Convenience Receptacle & Outlet Strip

☒ 6.3 CONFIGURATION

☒ 6.4 SERVICE DATA

☒ 6.5 ABSORBER INSPECTION & MAINTENANCE
☒ 6.5.1 Repack Manual Auto Valve - if applicable
☒ 6.5.9 Ultrasonic Flow Sensor - if applicable
☒ 6.5.10 Spiromed Sensor - if applicable

☒ 6.6 HIGH PRESSURE LEAK - DUE 12/04

6.7 BREATHING SYSTEM
☒ 6.7.1.8 Absorber & Fresh Gas Leak
☒ 6.7.1.9-14 Vaporizer Leak
☒ 6.7.1.16 Exclusion System Check
☒ 6.7.2 Vapor Config and Indicator Test
☒ 6.7.3 APL Valve Test
☒ 6.7.4 PEEP/ PEEP w/ Bypass Test
☒ 6.7.5 O2 Flush Test
☒ 6.7.6 Expiratory Valve Leak Test
☒ 6.7.7 Inspiratory Valve Leak Test
☒ 6.7.8 Bain Circuit - if applicable

6.8 OXYGEN ANALYZER
☒ 6.8.2 21% Calibration
☒ 6.8.4 System Alarm Silence
☒ 6.8.14 100% O2 Concentration

6.9 FLOWMETERS & GAS CONCENTRATIONS
☒ 6.9.1 Oxygen Flowmeter
☒ 6.9.2 Heliox Flowmeter & Heliox + O2 Concentration
☒ 6.9.3 CO2 Flowmeter & CO2 + O2 Concentration
☒ 6.9.4 AIR Flowmeter & AIR + O2 Concentration
☒ 6.9.5 N2O Flowmeter & N2O + O2 Concentration
☒ 6.9.6 ORC (w/ bypass) / ORMC @ 1, 2, 4 l/min O2
☒ 6.9.6.8 Minimum O2 Flow
☒ 6.9.6.9 N2O bypass flow @ Min. O2 - if applicable
☒ 6.9.7 Auxiliary O2 Flowmeter

6.10 HIGH PRESSURE REGULATORS
☒ 6.10.1 N2O Regulator
☒ 6.10.2 AIR Regulator
☒ 6.10.3 O2 Regulator

☒ 6.11 LOW O2 SUPPLY ALARM & SETTING - DUE 12/04

☒ 6.12 OXYGEN SUPPLY FAILURE PROTECTION

6.13 PRESSURE MONITOR
☒ 6.13.5 APNEA Pressure - Alarm
☒ 6.13.6 APNEA Pressure - Setting
☒ 6.13.8 CONTINUOUS PRESS - Alarm
☒ 6.13.9 CONTINUOUS PRESS - Setting
☒ 6.13.10 VENT PRESS HI Alarm & Setting
☒ 6.13.11 SUB ATM PRESSURE Alarm & Setting

6.14 VENTILATOR
☒ 6.14.15 I:E Ratio - Extended Range
☒ 6.14.16 I:E Ratio
☒ 6.14.19 PLC @ 30 cm H2O
☒ 6.14.20 PLC @ MIN
☒ 6.14.22 "REVERSE FLOW" - Alarm
☒ 6.14.28 APNEA VOL - Alarm
☒ 6.14.32 Flow Direction Check
☒ 6.14.33 Tidal Volume

6.15 BELLOWS - Adult/ Pediatric Int./ Pediatric Ext.
6.15.1 BELLOWS ADULT
☒ 6.15.1.1 1200 ml Tidal Volume
☒ 6.15.1.2 Bellows Inflation Check
☒ 6.15.1.7 Drive Gas Leakage
☒ 6.15.1.14 Max Tidal Volume
☒ 6.15.1.15 Relief Valve PEEP
☐ 6.15.1.21 200ml Tidal Volume

6.15.2 PEDIATRIC - EXTERNAL
☒ 6.15.2.4 Bellows Inflation Check
☒ 6.15.2.7 Max Tidal Volume
☒ 6.15.2.9 100 Tidal Volume
☒ 6.15.2.12 Relief Valve PEEP
☒ 6.15.2.19 Drive Gas Leakage

6.15.3 PEDIATRIC - INTERNAL
☒ 6.15.3.3 Bellows Inflation Check
☒ 6.15.3.6 Max Tidal Volume
☒ 6.15.3.8 100 Tidal Volume
☒ 6.15.3.10 Relief Valve PEEP
☒ 6.15.3.17 Drive Gas Leakage

6.16 SPO2/ PULSE
☒ 6.16.1 Nellcor
☐ 6.16.2 Novametrix

6.17 NIBP TESTS
☒ 6.17.1 Inflation Pressure Test
☒ 6.17.2 Inflation Time Test
☒ 6.17.3 NIBP Leak Test

6.18 CO2/ AGENT ANALYZER
☒ 6.18.1 Sample Flow Verification
☒ 6.18.2 Line Block Test
☒ 6.18.3 Analyzer Accuracy Test

☒ 6.19 OPEN RESERVOIR Cleaning & Testing - DUE 12/04
☐ 6.20 A/C SCAVENGER Cleaning & Testing - DUE n/a
☐ 6.21 BAG SCAVENGER Cleaning & Testing - DUE n/a

☒ 6.22 SUCTION REGULATOR DUE 12/04

☒ 6.23 MANUAL SPHYGMOMETER DUE 12/04

6.24 FINAL TESTS
☒ 6.24.1 Operator's Instruction Manual
☒ 6.24.3 Battery Test
☒ 6.24.5 Auxiliary Lamp

	SERIAL NUMBER	TYPE (H,E,I,S)	1.0 VOL % RIKEN	1.0 VOL % MULTI	2.5 VOL % RIKEN	2.5 VOL % MULTI	4.0 VOL % RIKEN	4.0 VOL % MULTI	RECOMMENDED FOR USE YES	RECOMMENDED FOR USE NO
VAPOR CONCENTRATION VERIFICATION	ARNF-0001	H	1.1	1.0	2.7	2.7	4.1	4.0	X	
	ARNF-0002	S	1.0	1.1	2.6	2.5	4.0	4.1	X	
	ARNF-0003	I	1.2	1.1	2.5	2.6	4.2	4.1	X	

TEST EQUIP.	DEVICE	CAL DUE	ID	DEVICE	CAL DUE	ID
	multi-meter	01/04	EL-1111			
	safety analyzer	03/04	ES-2222			
	flowmeter	02/04	FM-1111			
	manometer	01/04	PM-1111			

PARTS REPLACED

PARTS DESCRIPTION	PART NUMBER	WHSE	QTY	C/ C S/ N
HOSE	111111x	N/A	1	

RECOMMENDATIONS/ GENERAL COMMENTS

CERTIFICATION LEVEL	
LAST VISIT	A
THIS VISIT	A
NEXT VISIT DUE	12/03

T. S. R. Signature Joe Tech | I. D. No. E-001 | Time 1:35 am | Customer Signature Dr. Jones | Date 09/20/03

REGULATORY AFFAIRS

S010052 REV H

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

SP17505

Dräger medical
A Dräger and Siemens Company

TEST CERTIFICATE
Narkomed MRI/MRI-2

DrägerService is a division of Draeger Medical, Inc. 3122 Commerce Drive Telford, PA 18969 / USA (215) 721-5402 (800) 4-DRAGER (215) 723-5935 FAX

INSTITUTION GENERAL HOSPITAL
ADDRESS 123 MAIN STREET
CITY ANYTOWN STATE PA ZIP 18970
TELEPHONE (610) 368-4361

SOFTWARE VERSION NUMBER 1.11
MACHINE SERIAL NUMBER 4087
ROOM NUMBER 8
P.O. NUMBER 73684
DISPATCH NUMBER N/A

- [X] SP00073 Vapor 19 & 19.1 Service Procedures
- [X] K.I.S.S. Label
- [X] Verify Test Equipment Cal Due Dates

6.1 ELECTRICAL SAFETY TEST
- [X] 6.1.1 Circuit Isolation
- [X] 6.1.2 Ground Continuity
- 6.1.3. Leakage Current

Ground	Polarity		
[X] 6.1.3.2 Normal	Normal	25	µA
[X] 6.1.3.4 Open	Normal	0	µA
[X] 6.1.3.5 Normal	Reverse	25	µA
[X] 6.1.3.7 Open	Reverse	0	µA

- [ ] 6.2 SELF DIAGNOSTIC TEST - CORE-M
- [X] 6.2A Self Diagnostic - VPO
- [X] 6.2B Configuration - VPO

6.2C SERVICE DATA - VPO
- [X] 6.2C.3 Last Service Date 1/05/02
- [X] 6.2C.4 Hours Since Last Service 331
- [X] 6.2C.5 Total Hours 729
- [X] 6.2C.4 Reset Date

- [X] 6.3 BATTERY CIRCUIT TEST

6.4 HIGH PRESSURE LEAK TEST
- [X] 6.4.1 Yoke & Check Valve
- [X] 6.4.2 O2 High Press Leak Test
- [X] 6.4.3 N2O High Press Leak Test

6.5 HIGH PRESSURE REGULATOR TEST
- [X] 6.5.12 O2 High Pressure Regulator
- [X] 6.5.18 N2O High Pressure Regulator
- [X] 6.5.18 AIR High Pressure Regulator

6.6 GAUGES
- [X] 6.6.1 Cylinder Gauges
- [X] 6.6.2 Pipeline Gauges

6.7 O2 SUPPLY FAILURE PROTECTION TEST
- [X] 6.7.1.5 N2O OFPD (Cyl)
- [X] 6.7.1.10 N2O OFPD (Pipe)
- [X] 6.7.2.5 Air OFPD
- [X] 6.7.3.4 O2 Supp Press Alarm 37 psi

6.8 FLOWMETER TEST
- [X] 6.8.1 O2 Flowmeter
- [X] 6.8.1.7 O2 Flow; Min Flow 175 ml/min
- [X] 6.8.2 N2O Flowmeter
- [X] 6.8.3 Air Flowmeter
- [X] 6.8.4 Auxiliary O2 flowmeter

6.9 FRESHGAS LEAK TEST
- [X] 6.9.6 Fresh Gas Leak 45 cm H2O
- [X] 6.9.9 Vapor Leak 45 cm H2O

6.10 ABSORBER SYSTEM
- [X] 6.10.1 Absorber System Inspection
- [X] 6.10.2.8 Abs Leak Test 45 cm H2O
- [X] 6.10.3.4 APL Valve Test 2 cm H2O
- [X] 6.10.4.1 Expiration Valve Leak
- [X] 6.10.4.2 Inspiration Valve Leak
- [X] 6.10.4.3 Flow Direction

6.10A BAIN CIRCUIT
- [ ] 6.10A.7 Bain Circuit Leak _____cmH2O
- [ ] 6.10A.12 APL Valve

6.10B VAPOR EXCLUSION
- [ ] 6.10B.3 Lower Vaporizer
- [ ] 6.10B.6 Upper Vaporizer

6.11 CALIBRATION CORE M
- [ ] 6.11.5 Flow Calibration

6.11A CALIBRATION-VPO
- [X] 6.11A.3 O2 Offset Calibration
- [X] 6.11A.10 Baromed Calibration

6.12 OXYGEN CAL AND ALARM-CORE-M
- [ ] 6.12.4 O2 Lo Calibration _____% O2
- [ ] 6.12.6 O2 Alarms
- [ ] 6.12.4 O2 LO Calibration _____% O2
- [ ] 6.12.6 O2 Alarms
- [ ] 6.12.11 O2 Hi Calibration_____% O2

6.12A O2 MED - VPO
- [ ] 6.12A.6 O2 Calibration _____% O2
- [ ] 6.12A.9-22 O2 Alarms
- [ ] 6.12A.23 O2 Med Calibrations _____% O2

6.13 PRESSURE ACCURACY CORE-M
- [ ] 6.13.7 Pressure Accuracy
- [ ] 6.13.9 Pressure Hi Alarm

6.13A BAROMED - VPO
- [X] 6.13A.15 Apnea Mid Delay 15 sec
- [X] 6.13A.16 Apnea HI Delay 28 sec
- [X] 6.13A.18 Apnea Setting 10 cmH2O
- [X] 6.13A.21 Cont. Press Delay 15 sec
- [X] 6.13A.22 Continuous Setting 20 cmH2O
- [X] 6.13A.24 Vent Pressure High 65 cmH2O
- [X] 6.13A.27 Sub-Atm Pressure 9 cmH2O

6.14 VOLUME CORE-M
- [ ] 6.14.11 Apnea Vol Mid Alert Delay____sec
- [ ] 6.14.12 Apnea Vol Hi Alert Delay_____sec
- [ ] 6.14.21 Minute Vol Accuracy
- [ ] 6.14.28 Tidal Vol Accuracy
- [ ] 6.14.31 Respiratory Rate Hi Alert Alarm

6.14A ULTRASONIC FLOW SENSOR - VPO
- [X] 6.14A.6 Apnea Volume Mid 15 sec
- [X] 6.14A.7 Apnea Volume 30 sec
- [X] 6.14A.8 Minute Volume Low Alarm
- [X] 6.14A.24 Minute Volume Accuracy
- [X] 6.14.A.26 Reverse Flow Message

6.15 VENTILATOR TEST
- [X] 6.15.13 Peak Insp Press 64 cm H2O
- [X] 6.15.16 Insp Time 2.0 sec
- [X] 6.15.18 Exp Time 4.0 sec
- [X] 6.15.21 Extended Insp Time 4.0 sec
- [X] 6.15.23 Extended Expir Time 2.0 sec
- [X] 6.15.24 Vent Cycle Test

6.16 BELLOWS DRIVE GAS LEAK TEST
- [X] 6.16.8 Drive Gas Leak Flow 20 ml/min

6.17 "F" BELLOWS TEST
- [X] 6.17.6 200 Tidal Vol 200 ml
- [X] 6.17.8 1000 Tidal Vol 1000 ml
- [X] 6.17.12 Max Tidal Vol 1300 ml

6.18 VENT RELIEF VALVE TEST
- [X] 6.18.5 Max PEEP 2 cm H2O
- [X] 6.18.7 Tidal Vol Test

6.19 INSP PRESSURE LIMIT TEST
- [X] 6.19.5 Peak Pressure @ "MIN" 12 cm H2O
- [X] 6.19.7 Peak Pressure @ "30" 30 cm H2O
- [X] 6.19.9 Peak Pressure @ 'MAX" 50 cm H2O

6.20 O2 CONCENTRATION TEST
- [X] 6.20.1.14 O2 & N2O Concentration Test 66 % O2
- [X] 6.20.2.4 O2 & Air Concentration Test 75 % O2

6.21 O2 RATIO CONTROL TEST
- [X] 6.21.5 O2% @ 1l/min 25 % O2
- [X] 6.21.7 O2% @ 1.5l/min 25 %O2
- [X] 6.21.9 O2% @ 2l/min 25 % O2
- [X] 6.21.11 O2% @ 4l/min 25 % O2
- [X] 6.21.14 O2% @ 1l/min 25 % O2
- [X] 6.21.15 N2O Flow @ min O2 500 ml/min

6.22 O2 FLUSH & 100% O2 FINAL TEST
- [X] 6.22.14 O2 Flush Rate 55 l/min
- [X] 6.22.19 O2 Concentration 99 %
- [ ] 6.23 A/C SCAVENGER
- [X] 6.24 OPEN RESERVOIR SCAVENGER

6.25 SUCTION REGULATOR (if applicable)
- [ ] 6.25.7 Vacuum @ "Zero"
- [ ] 6.25.11 Vacuum @ 250mmHg

- [X] 6.26 FINAL CHECK

VAPOR CONCENTRATION VERIFICATION

SERIAL NUMBER	TYPE (H,E,I,S)	1.0 VOL. % RIKEN	2.5 VOL. % RIKEN	4.0 VOL. % RIKEN	RECOMMENDED FOR USE YES	NO
+ARCH-1234	H	1.07	2.53	4.11		
ARCK 9999	S	1.02	2.67	4.25		

TEST EQUIP.

DEVICE	CAL DUE	ID	DEVICE	CAL DUE	ID
BIOTEK 501	6/03	746	VOLUMETER	6/03	893
SENSYM.	6/03	782	FLOWMETER	6/03	400
RIKEN MODEL 1814	6/03	763			
TEST GAUGE	6/03	006			

PARTS REPLACED

PARTS DESCRIPTION	PART NUMBER	WHSE	QTY	C/CS/N
VENT RELIEF DIA	4110960	409	1	N/A

RECOMMENDATIONS/ GENERAL COMMENTS: SEE REVERSE SIDE CONDITION NUMBER 30

CERTIFICATION LEVEL	
LAST VISIT	B
THIS VISIT	B
NEXT VISIT DUE	9/02

John Green	E-409	Drew Jones, MD	6/6/02
Technical Service Representative Signature	I.D. No.	Customer Signature	Date

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

SP17506

Dräger medical
A Dräger and Siemens Company

NARKOMED 6000 SERIES
Anesthesia Systems

DrägerService is a division of Draeger Medical, Inc. 3122 Commerce Drive Telford, PA 18969 / USA (215) 721-5402 (800) 4-DRAGER (215) 723-5935 FAX

INSTITUTION GENERAL HOSPITAL
ADDRESS 123 MAIN STREET
CITY ANYTOWN STATE PA ZIP 18970
TELEPHONE (610) 368-4361 CONTACT Dr. Jones

SOFTWARE VERSION NUMBER 3.01
MACHINE SERIAL NUMBER 12385
ROOM NO. 8
P.O. NUMBER 73684
DISPATCH NUMBER D7643CF2

- ☒ Verify Test Equipment Due Dates
- ☒ Dräger Vaporizer Verification - SP00073
- ☒ DES Vaporizer Verification - SP00189

6.1 SERVICE MENU
- ☒ 6.1.11 6-Month Parts Kit - Due 12-02
- ☒ 6.1.11 1-Year Parts Kit - Due 06-03
- ☒ 6.1.11 2-Year Parts Kit - Due 06-04
- ☒ 6.1.11 3-Year Parts Kit - Due 06-03
- ☒ 6.1.14 Next PMC Due 09-02
- ☒ 6.1.19 O2 Zero Cal
- ☒ 6.1.20 Pressure Zero & Span Cal
- ☒ 6.1.21 Touch Screen Cal

6.2 PRESSURE MONITOR
- ☒ 6.2.3 APNEA Pressure Caution
- ☒ 6.2.4 APNEA Threshold
- ☒ 6.2.6 CONTINUOUS Pressure Warning
- ☒ 6.2.7 CONTINUOUS Threshold
- ☒ 6.2.8 VENT PRES HI Threshold
- ☒ 6.2.10 SUB ATM PRES Threshold

- ☒ 6.3 DUSTING & LINT CLEANING - Due 06-03
- ☒ 6.4 OPEN RESERVOIR CLEANING - Due 12-02
- ☐ 6.5 A/C SCAVENGER CLEANING - Due_____
- ☒ 6.6 DIVAN INSPECTIONS
- ☒ 6.6.25 CPU-1 Battery Replacement - Due 06-07
- ☒ 6.7 HIGH PRESSURE LEAK

6.8 FRESH GAS LEAK / EXCLUSION / SOLENOID / O2 FLUSH
- ☒ 6.8.3 Fresh Gas Leak
- ☒ 6.8.5 Left Vapor Leak
- ☒ 6.8.9 Right Vapor Leak
- ☒ 6.8.13 Upper Vapor Leak
- ☒ 6.8.16 Vapor Exclusion System
- ☒ 6.8.20 Control Solenoid Leak
- ☒ 6.8.24 O2 Flush Rate

6.9 DIVAN SERVICE MENU
- ☒ 6.9.1 Error Log
- ☒ 6.9.2 Confirm Mode Verification
- ☒ 6.9.3 Power Up Default Settings
- ☒ 6.9.4 Breathing System Heater
- ☒ 6.9.5 Pressure Sensor Zero Calibration
- ☒ 6.9.6 Pressure Sensor Linearity
- ☒ 6.9.7 Vacuum Relief Valve
- ☒ 6.9.8 PE3 Sensor / Control Pressure
- ☒ 6.9.9 Secondary Control Pressure
- ☒ 6.9.10 Expiratory Valve Leak
- ☒ 6.9.11 Inspiratory Valve Leak
- ☒ 6.9.12 Ventilator Override
- ☒ 6.9.13.3 Power-Up Divan Leak Rate

- ☒ 6.10 SUCTION SWITCH - Due 12-02
- ☒ 6.11 SUCTION REGULATOR - Due 12-02

6.12 OXYGEN ANALYZER
- ☒ 6.12.2 O2 Analyzer Concentration
- ☒ 6.12.9 O2 Analyzer O2 Calibration

6.13 FLOWMETERS/GAS CONCEN/EFG MEASURE
- ☒ 6.13.1 Oxygen Flowmeter
- ☒ 6.13.2 Air Flowmeter
- ☒ 6.13.3 Nitrous Oxide Flowmeter
- ☒ 6.13.4.2 O2 Ratio Control @ 4 L/min
- ☒ 6.13.4.4 O2 Ratio Control @ 2 L/min
- ☒ 6.13.4.6 O2 Ratio Control @ 1 L/min
- ☒ 6.13.5 Auxiliary Oxygen Flowmeter

6.14 HIGH PRESSURE REGULATOR - Due 12-02
- ☒ 6.14.1 N2O Regulator
- ☒ 6.14.2 Air Regulator
- ☒ 6.14.3 O2 Regulator

- ☒ 6.15 LOW O2 SUPPLY - Due 12-02

6.16 OXYGEN SUPPLY FAILURE PROTECTION
- ☒ 6.16.3 Minimum O2 Flow
- ☒ 6.16.5 N2O Flow @ Minimum O2 Flow
- ☒ 6.16.8 N2O & AIR - Oxygen Supply Protection

6.17 DIVAN OPERATING MODES
- ☒ 6.17.1 Mechanical Ventilation
- ☒ 6.17.1.13 APNEA VOL. Caution
- ☒ 6.17.1.14 Reverse Flow
- ☒ 6.17.1.19 Tidal Volume Accuracy
- ☒ 6.17.1.23 PEEP Set @ 20 cm H2O
- ☒ 6.17.1.25 PEEP Set @ 0 cm H2O
- ☒ 6.17.1.31 SIMV Synchronized Breath
- ☒ 6.17.1.34 Pres. Mode PEAK Pressure
- ☒ 6.17.2 Manual/Spont Ventilation

- ☒ 6.18 OPEN RESERVOIR PRESSURE RELIEF - Due 12-02
- ☐ 6.19 A/C SCAVENGER PRESSURE RELIEF - Due_____

6.20 GAS ANALYSIS POD (GAP)
- ☒ 6.20.1.4 Min Sample Flow
- ☒ 6.20.1.6 Max Sample Flow
- ☒ 6.20.1.9 CO2 Line Block
- ☒ 6.20.2.4 MEAN CO2
- ☒ 6.20.2.5 MEAN N2O
- ☒ 6.20.2.6 MEAN DES
- ☒ 6.20.2.9 APNEA CO2 Caution

6.21 GAS ANALYSIS POD (GAP2)
- ☒ 6.21.1.4 Low Sample Flow
- ☒ 6.21.1.6 Normal Sample Flow
- ☒ 6.21.1.9 CO2 Line Block
- ☒ 6.21.2.4 MEAN CO2
- ☒ 6.21.2.5 MEAN N2O
- ☒ 6.21.2.6 MEAN ISO
- ☒ 6.21.2.7 MEAN SEV
- ☒ 6.21.2.10 APNEA CO2 Caution

6.22 ELECTRICAL SAFETY
- ☒ 6.22.1 Ground Continuity
- ☒ 6.22.2 Circuit Isolation
- ☒ 6.22.3.3 Chassis Leakage Current

Ground	Polarity
☒ Normal	Normal 0 µA
☒ Open	Normal 90 µA
☒ Open	Reverse 90 µA
☒ Normal	Reverse 0 µA

- ☒ 6.22.4 Convenience Receptacle & Outlet Strip

6.23 FINAL CHECKS
- ☒ 6.23.3 Alarm Audio Silence
- ☒ 6.23.6 Primary Speaker Test
- ☒ 6.23.7 Backup Speaker Test
- ☒ 6.23.8 Battery Test
- ☒ 6.23.14 Divan Leak & Compliance Check
- ☒ 6.23.18 Operator's Instruction Manual

	SERIAL NUMBER	TYPE (H,D,E,I,S)	1.0 VOL. %	2.5 VOL. %	4.0 VOL. %	6.0 VOL. %	10.0 VOL. %	12.0 VOL. %	16.0 VOL. %	RECOMMENDED FOR USE YES	NO
VAPOR CONCENTRATION VERIFICATION	+AREJ 1234	H	1.07	2.53	4.11					X	
	AW614375	D			4.0	6.4	10.2	12.4	16.8	X	
	AREF2345	I	1.05	2.6	3.9					X	

TEST EQUIP.	DEVICE	CAL DUE	ID	DEVICE	CAL DUE	ID
	BIOTEK 501	09/02	7342	FLOWMETER	04/03	0081
	MULTI-METER	01/03	2733			
	SENSYM.	09/02	2212			
	RIKEN MODEL 18	08/02	0424			
	TEST GAUGE	02/03	0063			
	VOLUMETER	02/03	2300			

PARTS REPLACED

PARTS DESCRIPTION	PART NUMBER	WHSE	QTY	C/C S/N
Kit, PM NM60001Y	4115074-002	409	1	N/A

RECOMMENDATIONS/ GENERAL COMMENTS: NO RECOMMENDATIONS

CERTIFICATION LEVEL	
LAST VISIT	A
THIS VISIT	A
NEXT VISIT DUE	9/02

T. S. R. Signature: John Green | I. D. No.: E-409 | Time: 6:00pm | Customer Signature: Drew Jones, MD | Date: 06/06/02

4115093 REV F

REGULATORY AFFAIRS

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

SP175007

Dräger medical
A Dräger and Siemens Company

NARKOMED MOBILE / MILITARY ANESTHESIA SYSTEM

DrägerService is a division of Draeger Medical, Inc. 3122 Commerce Drive Telford, PA 18969 / USA (215) 721-5402 (800) 4-DRAGER (215) 723-5935 FAX

INSTITUTION GENERAL HOSPITAL
ADDRESS 123 MAIN STREET
CITY ANYTOWN STATE PA ZIP 18970
TELEPHONE (610) 368-4361 CONTACT Dr. Jones

SOFTWARE VERSION NUMBER 1.01
MACHINE SERIAL NUMBER 12385
ROOM NUMBER 8
P.O. NUMBER 73684
DISPATCH NUMBER D7643CF2

☒ Verify Test Equipment Due Dates
☒ SP00075 Relief Valve Diaphragm Due 9/23/03
☒ Dräger Vaporizer Verification SP00073
☒ DES Vaporizer Verification SP00091/SP00189

☒ **6.1 SELF DIAGNOSTICS**

6.2 ELECTRICAL SAFETY - DUE 9/23/03
☒ 6.2.1 Battery Check & Ground Continuity
☒ 6.2.2 Circuit Isolation
6.2.3.3 Chassis Leakage Current

	Ground	Polarity	
☒ 6.2.3.3.1	Normal	Normal 28	µA
☒ 6.2.3.3.2	Open	Normal 0	µA
☒ 6.2.3.3.3	Open	Reversed 30	µA
☒ 6.2.3.3.4	Normal	Reversed 0	µA

☒ **6.3 CONFIGURATION**

6.4 SERVICE DATA
☒ 6.4.8 Reset Service Date
☒ 6.4.10 Next Service - Due 9/23/03

6.5 CALIBRATIONS - DUE 3/01/04
☒ 6.5.3 O2 Analyzer Zero Calibration
☒ 6.5.11 Pressure Zero & Span Calibration

☒ **6.6 ABSORBER INSPECTION**
☒ 6.6.8 Ultrasonic Flow Sensor - Mobile
☒ 6.6.9 Spiromed Sensor - Military

☒ **6.7 HIGH PRESSURE LEAK**

6.8 BREATHING SYSTEM
☒ 6.8.1.9 Absorber & Fresh Gas Leak
☒ 6.8.1.11 Vaporizer Leak
☒ 6.8.2 APL Valve
☒ 6.8.3 O2 Flush
☒ 6.8.4 Exploratory Valve Leak Test
☒ 6.8.5 Inspiratory Valve Leak Test
☒ 6.8.6 Absorber PEEP Valve Test

6.9 OXYGEN ANALYZER
☒ 6.9.2 O2 Calibration
☒ 6.9.15 100% O2 Concentration

6.10 FLOWMETER & CONCENTRATIONS
☒ 6.10.1 Oxygen Flowmeter
☒ 6.10.2 Air Flowmeter & O2/Air Concentration
☒ 6.10.3 N2O Flowmeter & O2/N2O Concentration
☒ 6.10.4 ORC Tests @ 1, 2 & 4 l/min O2
☒ 6.10.5 Auxiliary Oxygen Flowmeter

6.11 HIGH PRESS. REG - DUE 3/01/04
☒ 6.11.1 N2O Regulator
☒ 6.11.2 O2 Regulator

☒ **6.12 LOW O2 SUPPLY - DUE** 3/01/04

6.13 O2 SUPPLY FAILURE PROTECTION
☒ 6.13.2 Minimum O2 Flow
☒ 6.13.4 N2O Bypass Flow @ Min. O2
☒ 6.13.7 O. F.P.D. Verification - All Gases

6.14 PRESSURE MONITOR
☒ 6.14.5 APNEA Pressure - Alarm
☒ 6.14.6 APNEA Pressure - Setting
☒ 6.14.8 Continuous Pres. - Alarm
☒ 6.14.9 Continuous Pres. - Setting
☒ 6.14.10 Vent. Pres. Hi - Alarm & Setting
☒ 6.14.11 Sub. Atm Pres. - Alarm & Setting

6.15 VENTILATOR
☒ 6.15.7 I:E Ratio - Extended Range
☒ 6.15.8 I:E Ratio
☒ 6.15.17 PLC @ 30
☒ 6.15.18 PLC @ MIN
☒ 6.15.20 Reverse Flow
☒ 6.15.30 Flow Direction Check
☒ 6.15.31 Tidal Volume
☒ 6.15.35 AIR/O2 Mode Switch

6.16 BELLOWS ADULT
☒ 6.16.1 1200 ml Tidal Volume
☒ 6.16.2 Bellows Inflation Check
☒ 6.16.7 Drive Gas Leakage
☒ 6.16.14 Max Tidal Volume
☒ 6.16.15 Relief Valve PEEP
☒ 6.16.21 200 ml Tidal Volume

6.17 SCAVENGER
☒ 6.17.1 Passive Mode
☒ 6.17.2 Suction Mode

6.18 FINAL TESTS
☒ 6.18.1 Operator's Instruction Manual

VAPOR CONCENTRATION VERIFICATION	SERIAL NUMBER	TYPE (H,E,I,S,D)	1.0 VOL % RIKEN	2.5 VOL % RIKEN	4.0 VOL % RIKEN	RECOMMENDED FOR USE YES	NO
	+ARCH-1234	H	1.07	2.53	4.11	X	
	ARCK 9999	S	1.02	2.67	4.25	X	

TEST EQUIP.	DEVICE	CAL DUE	ID	DEVICE	CAL DUE	ID
	BIOTEK 501	6/03	746			
	SENSYM.	6/03	782			
	RIKEN 1814	6/03	763			
	TEST GAUGE	6/03	006			
	FLOWMETER	6/03	893			
	VOLUMETER	6/03	400			

PARTS REPLACED

PARTS DESCRIPTION	PART NUMBER	WHSE	QTY	C/ C S/ N
VENT RELIEF DIA	4110960	409	1	

RECOMMENDATIONS/ GENERAL COMMENTS	SEE REVERSE SIDE CONDITION NUMBER 30

CERTIFICATION LEVEL	
LAST VISIT	N/A
THIS VISIT	B
NEXT VISIT DUE	1/1/03

T. S. R. Signature	John Green	I. D. No.	E-409	Time	6:00pm	Customer Signature	Drew Jones, MD	Date	6/5/02

SP17512

Dräger medical
A Dräger and Siemens Company

FABIUS TIRO
ANESTHESIA SYSTEM

DrägerService is a division of Draeger Medical, Inc. 3122 Commerce Drive Telford, PA 18969 / USA (215) 721-5402 (800) 4-DRAGER (215) 723-5935 FAX

INSTITUTION GENERAL HOSPITAL
ADDRESS 123 MAIN STREET
CITY ANYTOWN STATE PA ZIP 18970
TELEPHONE (215) 321-6543 CONTACT Dr. Smith

SOFTWARE VERSION NUMBER 2.0
MACHINE SERIAL NUMBER 11325
ROOM NUMBER 2
P.O. NUMBER 65829
DISPATCH NUMBER D7342BC1

8.1 ELECTRICAL SAFETY
☒ 8.1.1 Protective Ground Continuity
☒ 8.1.2 Circuit Isolation
☒ 8.1.3 Auxiliary Outlet ☐ n/a
☒ 8.1.4.3 Chassis Leakage Current
Open/Normal 9 µA
Normal/Normal 0 µA
Open/Reverse 9 µA
Normal/Reverse 0 µA
☒ 8.2 SYSTEM DIAGNOSTICS
☒ 8.3 BATTERY CIRCUIT
☒ 8.4 CONFIGURATION

8.5 SERVICE DATA
☒ 8.5.3 Last Service Date 7-10-03
Hours Since Service 100
Total Hours 200
Total Ventilator Hours 150
☒ 8.5.7 Ventilator O-Ring

8.6 CALIBRATIONS
☒ 8.6.4 Fresh Gas Flow
☒ 8.6.7 Pressure
☒ 8.6.9 O2 Offset
☒ 8.6.11 PEEP

8.7 SITE CONFIGURATIONS
☒ 8.7.2 O2 Position (virtual) R
☒ 8.7.3 Gas Selection 3
☒ 8.7.5 O2 Whistle ON
☒ 8.7.6 No Fresh Gas ON
☒ 8.7.7 Fresh Gas Low Alarm ON
☒ 8.7.8 Threshold Low Alarm ON
☒ 8.7.9 Ambient Pressure 1013 mbar
☒ 8.7.12 Serial Ports

☒ 8.8 SCAVENGER – AGS

8.9 BREATHING SYSTEM
☒ 8.9.1 Breathing System Inspection
☒ 8.9.1.1 Breathing System S/N ARCC-1263

8.9.2 FRESH GAS LEAK
☒ 8.9.2.6 Fresh G. Leak 25 cm/H2O
☒ 8.9.2.9 Fresh G. Lk w/vap 25 cm/H2O ☐ n/a

☒ 8.9.3 BREATHING SYSTEM

8.9.4 APL VALVE
☒ 8.9.4.6 APL Valve 10 cm/H20
☒ 8.9.4.7 APL Valve 10.40 cm/H20

8.9.5 INHALATION AND EXHALATION VALVES
☒ 8.9.5.6 Inh. valve leak 5 cc/min
☒ 8.9.5.12 Exh. valve leak 5 cc/min

8.9.6 FRESH GAS DECOUPLING VALVE
☒ 8.9.6.7 Fresh Gas Decl Valve Leak 5 ml/min

8.9.7 LEAKAGE CONTROL PORT
☒ 8.9.7.5 Leakge Control Port 5 cc/min

8.10 YOKES & GAUGES
☒ 8.10.1 Yokes & Gauges ☐ n/a
☒ 8.10.2 Cylinder Gauges ☐ n/a

8.11 GAS INLET REGULATOR OUTPUT
☒ 8.11.1.6 O2 Inlet Regulator 29 psi
☒ 8.11.2.4 N2O Inlet Reg. 29 psi ☐ n/a
☒ 8.11.3.4 O2 Pipeline Chk Valve 2 cc/min
☒ 8.11.3.6 N2O Pipeline Chk Valve 2 cc/min ☐ n/a

8.12 CYL. REGULATOR & PIPELINE GAUGES
☒ 8.12.1 N2O Cylinder Regulator ☐ n/a
☒ 8.12.1.8 N2O Cylinder Regulator 35 psi
☒ 8.12.2 N2O Gauge
☒ 8.12.2.4 N2O Gauge Accuracy
☒ 8.12.3.3 N2O Pipeline Leak 2 psi
☒ 8.12.4 Air Cylinder Regulator ☐ n/a
☒ 8.12.4.7 Air Cylinder Regulator 29 psi
☒ 8.12.5 Air Pipeline Gauge Accuracy
☒ 8.12.6.3 Air Pipeline Leak 2 psi
☒ 8.12.7 O2 Cylinder Regulator
☒ 8.12.7.7 O2 Cylinder Regulator 30 psi
☒ 8.12.8 O2 Pipeline Gauge Accuracy
☒ 8.12.9.2 O2 Pipeline Leak 2 psi

8.13 HIGH PRESSURE LEAK
☒ 8.13.1.6 O2 High Pressure Leak 2 psi
☒ 8.13.2.7 N2O High Pressure Leak 2 psi ☐ n/a

8.14 OXYGEN SUPPLY FAILURE PROTECTION
☒ 8.14.1 N2O ☐ n/a
☒ 8.14.2.5 O2 Supply Press. Alarm 20 psi
☒ 8.14.2.6 O2 SUPPLY LOW – Alarm

8.15 FLOWMETERS
☒ 8.15.1 O2 Flowmeter
☒ 8.15.2 N2O Flowmeter ☐ n/a
☒ 8.15.3 Air Flowmeter
☒ 8.15.4 Aux/O2 Flowmeter ☐ n/a
☒ 8.15.4.5 Aux/O2 leakage 50 cm/H2O
☒ 8.15.4.10 Aux/O2 Concentration 100%O2

☒ 8.16 OXYGEN MONITOR
☒ 8.16.12 INSP O2 LOW Alarm
☒ 8.16.20 INSP O2 HIGH Alarm
☒ 8.16.23 O2 Concentration 99 %O2

8.17 OXYGEN CONCENTRATIONS
☒ 8.17.1. O2/N2O Concentration ☐ n/a
☒ 8.17.1.5 O2/N2O Concentration 67 %O2
☒ 8.17.1.7 O2/N2O 4.2 L/min
☒ 8.17.1.8 Total Flowmeter 5.0 L/min
☒ 8.17.2 O2/Air Concentration
☒ 8.17.2.4 O2/Air Concentration 75 %O2

8.18 SORC
☒ 8.18.4 SORC@ 0.8L/minO2 25 %O2
☒ 8.18.6 SORC@ 1.5L/minO2 25 %O2
☒ 8.18.8 SORC@ 2.0L/min O2 25 %O2
☒ 8.18.10 SORC@ 10L/min O2 25 %O2
☒ 8.18.11 SORC Low Flow 0.6 L/min
☒ 8.18.13 SORC-N2O Lift-Off 0.1 L/min

☒ 8.19 PRESSURE MONITOR
☒ 8.19.13 APNEA PRESSURE (med) 15 sec
☒ 8.19.14 APNEA PRESSURE (high) 30 sec
☒ 8.19.16 Apnea P. Setting 8 cm/H2O
☒ 8.19.19 CONT. PRES. 15 sec
☒ 8.19.20 Cont. Pres. Setting 17 cm/H2O
☒ 8.19.22 Aw PRES. HIGH Alarm 40 cm/H2O
☒ 8.19.25 PRES. NEG. Alarm -8 cm/H2O

8.20 VENTILATOR
☒ 8.20.1 Manual Ventilation
☒ 8.20.2 Spontaneous Breathing
☒ 8.20.3 Flow Sensor Zeroing
☒ 8.20.4 Ventilator Delivery
☒ 8.20.4.11 Volume Delivery @ 380Vt 390 mL/min
☒ 8.20.4.12 Volume Accuracy
☒ 8.20.5.2 PEEP Accuracy
☒ 8.20.6.3 Pmax Accuracy
☒ 8.20.7.4 APL Accuracy @ 40 cm/H2O 39 cm/H2O
☒ 8.20.7.6 APL Accuracy @ Spont 0 cm/H2O
☒ 8.20.10 Pressure Limit Valve 75 cm/H2O
☒ 8.20.11.1 Auxiliary Air Valve -8.2 cm/H2O
☒ 8.20.12.3 Vacuum Pressure 198 cm/H2O

8.21 VOLUME ALARMS
☒ 8.21.6 MINUTE VOLUME LOW
☒ 8.21.9 APNEA FLOW (med) 15 sec
☒ 8.21.10 APNEA FLOW (high) 30 sec
☒ 8.21.12 FLOW SENSOR FAIL Alarm
☒ 8.21.17.3 Fresh Gas Low / No Fresh Gas Alarms
☒ 8.22 Audio Silence

8.23 Oxygen Flush
☒ 8.23.8 Oxygen Flush 100 %O2
☒ 8.23.12 Oxygen Flush Rate 48 L/min

8.24 Final Tests
☒ 8.24.1 Operator's Manual
☒ 8.24.2 Lamp Test
☒ 8.24.3 Final Check

VAPOR CONCENTRATION VERIFICATION	SERIAL NUMBER	TYPE (H,E,I,S)	1.0 VOL % RIKEN	1.0 VOL % MULTI	2.5 VOL % RIKEN	2.5 VOL % MULTI	4.0 VOL % RIKEN	4.0 VOL % MULTI	RECOMMENDED FOR USE YES	RECOMMENDED FOR USE NO
	+ARCH-1234	H	1.07		2.53		4.11		X	
	ARCK 9999	S	1.02		2.67		4.25		X	

TEST EQUIP.	DEVICE	CAL DUE	ID	DEVICE	CAL DUE	ID
	BIOTEK 501	11/02	746	VOLUMETER	11/02	893
	SENSYM.	11/02	782	FLOWMETER	11/02	400
	RIKEN 1814	10/02	763			
	TEST GAUGE	4/02	006			

PARTS REPLACED

PARTS DESCRIPTION	PART NUMBER	WHSE	QTY	C/C S/N

RECOMMENDATIONS/ GENERAL COMMENTS: NO RECOMENDATIONS

CERTIFICATION LEVEL	
LAST VISIT	A
THIS VISIT	A
NEXT VISIT DUE	7/04

T. S. R. Signature John Green | I. D. No. E-315 | Time 5:30pm | Customer Signature Drew Jones, MD | Date 1/4/03

4118460 REV A

☐ REGULATORY AFFAIRS

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

Only the owner of the equipment, with user input, can decide suitability for use within a particular environment. Draeger Medical offers the following recommendations for your consideration.

EQUIPMENT CONDITION	**	DRAEGER MEDICAL RECOMMENDATIONS	CERTIFICATION LEVEL
4. * No touch-coded oxygen flow control knob.	II	Install touch-coded oxygen flow control knob.	D
11. Ventilator is equipped with descending bellows and lacks integrated CO2 monitoring, or fresh gas low alarm.	I	Install an ascending bellows. With the continued use of descending bellows, it is absolutely mandatory that the system is only used with constant monitoring of the patient's exhaled CO2.	D
14. CO2/Agent monitor exhaust port is not properly connected to waste gas disposal system.		Connect monitor exhaust port to waste gas disposal system.	B
16.* Vaporizer installed downstream from fresh gas outlet.		Remove vaporizer from downstream position and replace fresh gas hose.	D
18.* No waste gas disposal system.		Issue Departmental Alert. Recommend the installation of an appropriate scavenger system.	D
19.* No 19mm or 30mm hose terminals for scavenger hose connections.	I	Replace obsolete hose connections on waste gas disposal system.	D
21. No ventilator pressure limit control.		Install ventilator pressure limit control on "F" style bellows.	B
25. PEEP device on 22mm terminal of expiratory valve.		Issue Department Alert. Remove PEEP device. Install integrated absorber PEEP with bypass valve.	D
27. Ventilator bellows has a PEEP Valve.		Remove the ventilator bellows PEEP valve and convert to integrated absorber PEEP valve with bypass valve.	B
30. Anesthesia machine is equipped with inhalation anesthesia vaporizers without an agent monitor in the breathing system.		Install an agent monitor, or a Vitalert 3000 series patient monitor. (Use only MRI compatible monitor where applicable.)	B
31. Anesthesia machine is equipped with a TEC 6 Desflurane or Draeger Sevoflurane vaporizer, and the 4600 three agent analyzer is indicating another agent when Sevoflurane, or Desflurane are selected.		Upgrade three gas agent analyzer to a 4610 five gas analyzer, or remove the Desflurane, and, or the Sevoflurane vaporizer.	D

* Denotes a hazard that is substantially diminished by anesthesia machines complying with current applicable standards for components used in anesthesia systems.

Please refer to page 9-12 in Draeger Medical's Safety guidelines Anesthesia System Risk Reduction manual. (white book located in the storage drawer of the machine or available upon request)

** ADDITIONAL RECOMMENDATIONS

I The system in its present configuration shall only be used with a CO2 monitor incorporating an apnea warning. The operator of the system is advised to frequently scan the CO2 readings and alarm thresholds.

II The present configuration of equipment requires that the unit operate at all times with an oxygen analyzer that includes a low oxygen warning. The operator of the system is advised to frequently scan the oxygen readings and alarm limits.

CERTIFICATION LEVEL

B - Certified with Recommendations
D - No Certification

SP17508

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

SP17509

IMMEDIATELY CODE D

WARNING

THIS SYSTEM IS NOT CERTIFIED

Refer to the Periodic Manufacturer's checklist and Executive Summary reports for details regarding this inspection.
Only the owner of this equipment, with user input, can decide suitability for use within a particular environment.

Date: 3/4/02 Next Visit Due: 6/02

Authorized Signature: John M. Green

Dräger medical
A Dräger and Siemens Company

4114857

Dräger medical
A Dräger and Siemens Company

Periodic Manufacturer's Certification

Serial Number: 11583

A ⇨ ☑ Certified — Time: 7:35 a.m. (p.m.)
B ⇨ ☐ Certified w/ recommendations — Date: 8/10/02
C ⇨ ☐ Conditionally Certified ☐ I ☐ II — Next Visit Due: 11/02

Certified represents proper operating condition per manufacturer's specification at the time that inspection and validation were completed. Refer to Periodic Manufacturer's Certification and Executive Summary reports for details regarding DMI recommendations and Conditional certification.

Authorized Signature: John M. Green

S010007

Dräger medical
A Dräger and Siemens Company

Periodic Manufacturer's Certification

Serial Number: 11583

A ⇨ ☐ Certified — Time: 7:35 a.m. (p.m.)
B ⇨ ☑ Certified w/ recommendations — Date: 8/10/02
C ⇨ ☐ Conditionally Certified ☐ I ☐ II — Next Visit Due: 11/02

Certified represents proper operating condition per manufacturer's specification at the time that inspection and validation were completed. Refer to Periodic Manufacturer's Certification and Executive Summary reports for details regarding DMI recommendations and Conditional certification.

Authorized Signature: John M. Green

S010006

Call **1-800-543-5047** for service

Dräger medical
A Dräger and Siemens Company

Periodic Manufacturer's Certification

Serial Number: 11583

A ⇨ ☐ Certified — Time: 7:35 a.m. (p.m.)
B ⇨ ☑ Certified w/ recommendations — Date: 8/10/02
C ⇨ ☑ Conditionally Certified ☐ I ☐ II — Next Visit Due: 11/02

Certified represents proper operating condition per manufacturer's specification at the time that inspection and validation were completed. Refer to Periodic Manufacturer's Certification and Executive Summary reports for details regarding DMI recommendations and Conditional certification.

Authorized Signature: John M. Green

S010007

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

CAUTION: AFTER FILLING HAS BEEN COMPLETED, REINSERT PLUG INTO UPPER FILLER PORT AND TIGHTEN LOCKING SCREW

4112520-001

CAUTION

DO NOT USE!

THIS UNIT DOES NOT PERFORM WITHIN FACTORY SPECIFICATIONS

REFER TO SERVICE DOCUMENTATION FOR DETAILS

4114327

WARNING

- THE ADMINISTRATION OF DESFLURANE ANESTHESIA MAY REQUIRE FRESH GAS CONCENTRATIONS HIGHER THAN COMMONLY USED WITH OTHER VOLATILE ANESTHETIC AGENTS. O_2 FRESH GAS CONCENTRATION OF LESS THAN 21% MAY BE OBTAINED WITH HIGH VAPORIZER SETTINGS. CONTINUOUS MONITORING OF THE O_2 CONCENTRATION IN THE BREATHING SYSTEM IS THEREFORE REQUIRED.

- NORTH AMERICAN DRÄGER RECOMMENDS THE CONTINUOUS MONITORING OF THE CONCENTRATION OF ANESTHETIC VAPORS IN THE BREATHING SYSTEM DURING THE ADMINISTRATION OF INHALATION ANESTHESIA.

4112737-001 SP17511

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

SP17510

Dräger medical
A Dräger and Siemens Company

3122 Commerce Drive
Telford, PA 18969 / USA
(215) 721-5402
(800) 543-5047
(215) 723-5935 FAX

NOTICE

☐ A Periodic Manufacturer's Certification (PMC) has been performed on this anesthesia machine and it is possible that during the service procedure, settings of the controls, patient circuit components, and other auxiliary devices may have been changed. Please check the machine for proper setup prior to clinical use.

☐ It is possible that the vaporizers on this anesthesia machine are empty and require filling. Please check before clinical use.

☐ PMC and Executive Summary Reports have been prepared for this anesthesia machine. Please refer to these reports for compliance to any possible recommendations.

☐ The Operator's Manual for this anesthesia machine is located in the equipment storage drawer.

☐ We were unable to locate the Operator's Manual for this anesthesia machine. Please contact our Technical Service Department at 1-800-543-5047 if the manual for this type of machine is not on file with the institution.

☐ ⚠ WARNING: THIS SYSTEM IS NOT CERTIFIED
Refer to the Periodic Manufacturer's checklist and Executive Summary reports for details regarding this inspection. Only the owner of this equipment, with user input, can decide suitability for use within a particular environment.

NOTE: REMOVE NOTICE BEFORE CLINICAL USE

S010011

THE CONCENTRATION OUTPUT OF THIS VAPORIZER SHALL BE VERIFIED AFTER IT HAS BEEN ATTACHED TO THE ANESTHESIA MACHINE

S010015

Dräger medical
A Dräger and Siemens Company

Periodic Manufacturer's Certification

Serial Number:_____

A ⇨ ☐ Certified — Time:_____a.m. p.m.
B ⇨ ☐ Certified w/ recommendations — Date:_____
C ⇨ ☐ Conditionally Certified ☐I ☐II — Next Visit Due: _____

Certified represents proper operating condition per manufacturer's specification at the time that inspection and validation were completed. Refer to Periodic Manufacturer's Certification and Executive Summary reports for details regarding DMI recommendations and Conditional certification.

Authorized Signature: _____ S010006

Call **1-800-543-5047** for service

S010006

Dräger medical
A Dräger and Siemens Company

Periodic Manufacturer's Certification

Serial Number:_____

A ⇨ ☐ Certified
B ⇨ ☐ Certified w/ recommendations
C ⇨ ☐ Conditionally Certified ☐I ☐II

Certified represents proper operating condition per manufacturer's specification at the time that inspection and validation were completed. Refer to Periodic Manufacturer's Certification and Executive Summary reports for details regarding DMI recommendations and Conditional certification.

Authorized Signature: _____

S010007

S010007

VAPORIZER VERIFICATION

Dräger medical
A Dräger and Siemens Company

NAME: _____ DATE: _____
TYPE: HAL ENF ISO SEVO DES

☐ NO AGENT TO TEST	6% =
1% =	10% =
2.5% =	12% =
4% =	16% =

☐ PASS ☐ FAIL

S010016

CHAPTER IV

STANDARD COMPLIANCE

The design, production and performance of the various devices utilized in an anesthesia system are frequently subject to standards. These standards are voluntary and manufacturer's are not obligated to comply with them. Certain local ordinances, however, may require specific compliance. It is the intention of most of the standards to obligate manufacturers to comply with certain minimum safety requirements but it is a further intention to provide for compatibility and interchangeability of certain components of the breathing system such as hoses, Y-pieces, connectors and adapters.

The following represents a listing of standards which deal with the components of an anesthesia system. The listing is not intended to be complete due to the ongoing process of the introduction of new standards and sometimes the overlapping activities of different standard organizations addressing the same device.

APPLICABLE STANDARDS FOR THE COMPONENTS USED IN ANESTHESIA SYSTEMS

1. American National Standards Institute (ANSI)
   11 West 42nd Street
   New York, NY 10036, USA
   Phone: (212) 642-4900
   Fax: (212) 302-1286

   ANSI/ASME B40.1- 1991 Gauges - Pressure Indicating Dial Type - Elastic Element

2. American Society for Testing and Materials (A.S.T.M.)
   100 Barr Harbor Drive
   West Conshohocken, PA 19428, USA
   Phone: (610) 832-9585
   Fax: (610) 832-9555

   Note: Year shown in Brackets is year the standard was reapproved.

   F 960-86 (1993) Standard Specification for Medical and Surgical Suction and Drainage Systems
   F 1054-87 (1994) Standard Specification for Conical Fittings of 15 mm and 22 mm Sizes
   F 1101-90 (1996) Standard Specification for Ventilators Intended for Use During Anesthesia
   F 1161-88 (1994) Standard Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines
   F 1204-88 (1993) Standard Specification for Anesthesia Reservoir Bags
   F 1205-88 (1993) Standard Specification for Anesthesia Breathing Tubes
   F 1208-89 (1994) Standard Specification for Minimum Performance and Safety Requirements for Anesthesia Breathing Systems
   F 1343-91 Standard Specification for Anesthetic Equipment - Scavenging Systems for Anesthetic Gases
   F 1415-92 Standard Specification for Pulse Oximeters
   F 1452-92 Standard Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthetic Gas Monitors
   F 1456-92 Standard Specification for Capnometers
   F 1462-93 Standard Specification for Oxygen Analyzers
   F 1463-93 Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care
   F 1850 Standard Specification for Particular Requirements for Anesthesia Workstations and their Components

   A.S.T.M. Standards Under Development:
   F1850-98aCorrigendum

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

STANDARD COMPLIANCE (CONTINUED)

3. Compressed Gas Association (CGA)
   1725 Jefferson Davis Highway, Suite 1004
   Arlington, VA 22202-4102
   Phone: (703) 412-0900
   Fax: (703) 412-0128

   ANSI/CGA E7-1992American Ntl. Standard for Medical Gas Regulators and Flowmeters

Pamphlet C-9-1988 (Reaffirmed 1993)	Standard Color Marking of Compressed Gas Containers Intended for Medical Use
Pamphlet V-1-1994	Compressed Gas Cylinder Valve Outlet and Inlet Connections
Pamphlet G-4.3-1994	Commodity Specification for Oxygen
Pamphlet G-7-1990	Compressed Air for Human Respiration
Pamphlet V-5-1989	Diameter Index Safety System
Pamphlet P-2-1996	Characteristics and Safe Handling of Medical Gases
Pamphlet P-14-1992	Accident Prevention in Oxygen-Rich and Oxygen Deficient Atmospheres

4. National Fire Protection Association (NFPA)
   1 Batterymarch Park
   Quincy, MA 02269
   Phone: (617) 770-3000 or 1-800-344-3555
   Fax: 1-800-593-6372

NFPA 99	Standard for Health Care Facilities - 1999 Edition
NEC	National Electrical Code 1999

5. Underwriters Laboratories, Inc. (UL)
   333 Pfingston Road
   Northbrook, IL 60062-2096
   Phone: (847) 272-8800

UL 252	Standard for Safety, Compressed Gas Regulators
UL 544	Standard for Safety, Medical and Dental Equipment
UL 2601-1	Standard for Safety, Medical Electrical Equipment, Part 1: General Requirements for Safety

6. Association for the Advancement of Medical Instrumentation (AAMI)
   3330 Washington Boulevard, Suite 400
   Arlington, VA 22201-4598
   Phone: (703) 525-4890
   Fax: (703) 276-0793

   ANSI/AAMI ES-1-1993 Safe Current Limits for Electromedical Equipment

B. FOREIGN STANDARDS

1. Canadian Standards Association (CSA)
   178 Rexdale Boulevard
   Etobicoke, Ontario, Canada M9W 1R3
   Phone: (416) 747-4044

C22.2 No. 125-M1984 (1996)	Electromedical Equipment
CAN/CSA-C22.2 No. 601.1-M90 (1997)	Medical Electrical Equipment, Part 1: General Requirements for Safety
CAN/CSA-C22.2 No. 601.1S1-94	Supplement No. 1-94 to CAN/CSA C22.2 No. 601.1-M90, [Adopted IEC 601-1, Amendment 1 (1994)]

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

STANDARD COMPLIANCE (CONTINUED)

CAN/CSA-C22.2 No. 601.1.1-94	Medical Electrical Equipment, Part 1: General Requirements for Safety - 1. Collateral Standard: Safety Requirements Medical Electrical Systems
CAN/CSA-C22.2 No. 601.2-94	Medical Electrical Equipment, Part 1: General Requirements for Safety - 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Test
CAN/CSA-C22.2 No. 601.2.13-94	Anaesthetic Machines
CAN/CSA-ISO 7767-98	Oxygen Monitors for monitoring patient breathing mixtures - Safety Requirements (Adopted ISO 7767-97)
CAN/CSA-ISO 9703.1-97	Anaesthesia and Respiratory Care Alarm Signals - Part 1: Visual Alarm Signals (Adopted ISO 9703.1-92)
CAN/CSA-ISO 9703.2-97	Anaesthesia and Respiratory Care Alarm Signals - Part 2: Auditory Alarm Signals (Adopted ISO 9703.2-94)
CAN/CSA-ISO 11196-98	Anaesthetic Gas Monitors
Z168.3-97	Anaesthesia Machines for Medical Use
Z168.5.1-97	Anaesthesia Ventilators
CAN/CSA-Z168.6-M89	Oxygen Analyzers
CAN3-Z168.8-M82 (R1994)	Anaesthetic Gas Scavenging Systems
CAN/CSA-Z168.9-92	Breathing Systems for Use in Anaesthesia
Z168.11-94	Vacuum Devices for Suction and Drainage
CAN/CSA-Z305.1-92	Nonflammable Medical Gas Piping Systems
CAN/CSA-Z305.2-M88 (R1997)	Low-Pressure Connecting Assemblies for Medical Gas Systems
CAN/CSA-Z305.3-M87 (R1997)	Pressure Regulators, Gauges, and Flow-Metering Devices for Medical Gases
CAN/CSA-Z5360-94	Anaesthetic Vaporizers - Agent Specific Filling Systems (Adopted ISO 5360-93)
CAN/CSA-Z9919-94	Pulse Oximeters for Medical Use - Requirements
CAN/CSA - ISO 8835-3-98	Anaesthetic Gas Scavenging Systems

2. International Electrotechnical Commission (IEC)*
   3, rue de Varembé
   PO Box 131
   1211 Geneva 20
   Switzerland
   Phone: +41 22 919 02 11
   Fax: +41 22 919 03 00

IEC 601-1: 1988	Medical Electrical Equipment - Part 1, General Requirements for Safety
IEC 601-1-1: 1992	Medical Electrical Equipment - Part 1, General Requirements for Safety, 1. Collateral Standard Safety requirements for medical electrical systems
IEC 601-1-2: 1993	Medical Electrical Equipment - Part 1, General Requirements for Safety, 2. Collateral Standard: Electromagnetic Compatibility
IEC 601-1-4: 1996	Medical Electrical Equipment - Part 1, General Requirements for Safety, 4. Collateral Standard: Programmable electrical medical systems
IEC 601-2-13: 1998	Medical Electrical Equipment - Part 2: Particular requirements for the safety of anaesthetic machines

3. International Standards Organization (ISO)*
   1, rue de Varembé
   Case postale 56
   CH-1211 Geneva 20
   Switzerland
   Phone: +41 22 749 01 11
   Fax:+41 22 733 34 30

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

STANDARD COMPLIANCE (CONTINUED)

ISO 5145: 1990	Cylinder valve outlets for gases and gas mixtures - Selection and dimensioning
ISO 5356-1: 1996	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
ISO 5356-2: 1987	Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw threaded, weight-bearing fittings
ISO 5359: 1989	Low pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems
ISO 5360: 1993	Anaesthetic vaporizers - Agent specific filling systems
ISO 5362: 1986	Anaesthetic reservoir bags
ISO 5367: 1991	Breathing tubes intended for use with anaesthetic apparatus and ventilators
ISO 7396: 1987	Nonflammable medical gas pipeline systems
ISO 7767: 1997	Oxygen analyzers for monitoring patient breathing mixtures - safety requirements
ISO 8835-2: 1993	Inhalational anaesthesia systems - Part 2: Anaesthetic circle breathing systems
ISO 8835-3: 1997	Inhalational anaesthesia systems - Part 3: Anaesthetic gas scavenging systems - Transfer and receiving systems
ISO 9170: 1990	Terminal units for use in medical gas pipeline systems
ISO 9703-1: 1992	Anaesthesia and respiratory care alarm signals - Part 1: Visual alarm signals
ISO 9703-2: 1994	Anaesthesia and respiratory care alarm signals - Part 2: Auditory alarm signals
ISO 9918: 1993	Capnometers for use with humans - Requirements
ISO 9919: 1992	Pulse oximeters for medical use - Requirements
ISO 10079-3: 1992	Medical suction equipment - Part 3: Suction equipment powered from vacuum or pressure source
ISO 10524	Pressure regulators and pressure regulators with flow metering devices for medical gas systems
ISO 111196:1995	Anaesthetic gas monitors

*In the United States of America these international standards can be purchased from:
American National Standards Institute (ANSI)
11 West 42nd Street
New York, NY 10036, USA
Phone: (212) 642-4900
Fax: (212) 302-1286

The risk manager of a hospital or the biomedical engineering department may be interested in obtaining these standards in order to develop a better understanding of the equipment in his possession or to aid in the decision making process for purchasing new equipment.

There are in general three important sections in a standard; the Requirements, the Test Procedures and the rationale. While the requirements of the standard are normally easy to understand, some additional information must be provided for the test procedures. The test procedure in a standard applies to "type testing" only. Manufacturer's in general will not test every single unit for compliance with this "type test". Furthermore, the manufacturer's effort is aimed towards complying with the test specifications when the device leaves his custody but the tolerances stated in the specification manual for in-field testing after use may be wider.

The rationale section of a standard contains helpful information for the risk manager of a hospital. In many cases it will address and state the reasons for the requirement and by doing so may educate the reader concerning possible hazards contained in equipment when not complying with a standard. In standard terminology "MAY" denotes an optional feature, "SHOULD" denotes a desirable, but not mandatory feature, while "SHALL" denotes a mandatory feature.

It is not the intention of the authors to recommend an ongoing updating of equipment whenever new standards are released or existing standards are updated. It must be further understood that equipment does not become automatically obsolete when different standards are published. It is up to the department to make an evaluation if noncompliance with a certain standard requirement will present a potential risk and if any measures such as modification(s) or education are required to reduce this risk.

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

22 July 2002

3122 Commerce Drive
Telford, PA 18969
Telephone: (215) 721-5402
(800) 543-5047
Facsimile: (215) 723-5935

Dräger medical
A Dräger and Siemens Company

EXECUTIVE SUMMARY

Test Vigilance
123 Telford Ave
Telford, PA 18961

RE: Periodic Manufacturer's Certification Summary
Dispatch Number: JHE45ERGX

Dear Valued Customer,

I have completed a Periodic Manufacturer's Certification on your anesthesia systems under service contract with Draeger Medical, Inc.. The Periodic Manufacturer's Certification is a program implemented to advise you of the current condition of your equipment and of the upgrades that may be made to meet the current applicable standards as well as to assist your facility in deciding the suitability for use within a particular environment. Attached herewith, is each machine/monitor that was examined as well as our recommendations for each. Please refer to the following symbols if they apply.

* Denotes a hazard that is greatly diminished by anesthesia machines complying with applicable standards for components used in anesthesia systems. Refer to Pages 9 - 12 in the North American Dräger Safety Guidelines and Risk Reduction manual.

! Denotes an equipment condition for a machine that will not be certified by the manufacturer after June 1, 1999.

I The system in its present configuration shall only be used with a CO2 monitor incorporating an apnea warning. The operator of the system is advised to frequently scan the CO2 readings and the alarm thresholds.

II The present configuration of the equipment requires that the unit operate at all times with an oxygen analyzer that includes a low oxygen warning. The operator of the system is advised to frequently scan the oxygen readings and alarm limits.

Since many of our service calls are made after normal operating room working hours and key personnel may be unavailable, it is incumbent upon the recipient of this letter and its appropriate attachments, to forward it to the Chief of Anesthesia and/or Risk Manager at your facility. Please review these documents carefully and sign below as an acknowledgment that you have reviewed this information.

Sincerely,

Technical Service Representative

Customer Signature: _____ Date: _____

PERIODIC MANUFACTURER'S CERTIFICATION (continued)

Dräger medical
A Dräger and Siemens Company

	Dispatch Number: JHE45ERGX	**22 July 2002**
Only the owner of the equipment with user input can decide its suitability for use within its particular environment. NAD offers the following recommendations for your consideration.		

MACHINE TYPE: Narkomed 2B **Equipment Condition**	**SERIAL NUMBER: TEST3** **Recommendation**
PEEP device on 22mm terminal of expiratory valve. *Anesthesia machine is equipped with inhalation anesthesia vaporizers without an agent monitor in the breathing system.* *Enflurane Agent is unavailable for tests.*	*Issue Department Alert. Remove PEEP device. Install integrated absorber PEEP with bypass valve.* *Install an agent monitor or a Vitalert 3000 series patient monitor.* *Add agent or remove vaporizer.*
MACHINE TYPE: Narkomed 4 **Equipment Condition**	**SERIAL NUMBER: TEST4** **Recommendation**
Integrated absorber system PEEP valve does not have the bypass valve.	*Install integrated absorber PEEP valve with bypass valve.*
MACHINE TYPE: Narkomed 6000 **Equipment Condition**	**SERIAL NUMBER: TEST5** **Recommendation**
No Recommendations	*No Recommendations*

End of Executive Summary

RETURN TO SERVICE PROCEDURE TABLE OF CONTENTS
RETURN TO CD-ROM TABLE OF CONTENTS

RETURN TO SERVICE PROCEDURE TABLE OF CONTENTS
RETURN TO CD-ROM TABLE OF CONTENTS

Dräger medical

A Dräger and Siemens Company

DrägerService is a division of
Draeger Medical, Inc.
3122 Commerce Drive
Telford, PA 18969
Tel: (215) 721-5402
(800) 543-5047
Fax: (215) 721-5784
Web: www.draegermedical.com
Printed in the U.S.A.